

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN**

UNITED STATES OF AMERICA,)
Petitioner,) Civ. Action No. 14-MC-77
v.)
AURORA HEALTH CARE, INC.,)
Respondent.)

)
**OPPOSITION TO
UNITED STATES' PETITION
TO ENFORCE CIVIL
INVESTIGATIVE DEMAND**

INTRODUCTION

The Government asks the Court to force Aurora Health Care, Inc. (“Aurora”), to produce documents that its medical staff and others created in furtherance of their mandate to improve patient care and hospital conditions. The Government’s motion should be denied because the documents are protected from disclosure under Wisconsin state statute and were created in reliance upon that protection. The documents are also exempt from discovery under Supreme Court precedent and the federally recognized self-critical evaluation privilege. Moreover, the Government’s need for the documents is minimal because, under both state and federal law, any peer review related actions that Aurora and its physicians took cannot serve as a basis for liability. Therefore, Aurora respectfully requests the Government’s petition be denied.

FACTS

Aurora received a 17-page Civil Investigative Demand (“CID”) ordering Aurora to produce 25 categories of documents. The Government’s expansive requests are set forth in the CID filed under seal.

Over the course of the past year, Aurora has worked closely with the United States Attorney's Office to comply with the Government's demands. To date, Aurora has produced over 60,000 pages of records without objection.¹ Aurora did, however, inform the Government that it was prohibited from producing certain documents that fall within the scope of the statutory protections set forth in Wisconsin Statutes §§ 146.37; 146.38. Aurora advised the Government that it would not produce the documents because, in reliance on the protections afforded by Wisconsin law, Aurora promises its physicians that the documents created in accordance with the statute would be maintained in confidence. (Declaration of Jeffrey Smith, M.D. in Opposition to United States' Petition to Enforce Civil Investigative Demand ("Smith Decl.") at ¶ 5.)

ARGUMENT

I. WISCONSIN LAW PROHIBITS DISCLOSURE OF THE REQUESTED DOCUMENTS.

Wisconsin law forbids Aurora from disclosing certain documents that are covered by statute under penalty of law. Wisconsin § 146.38 (1m); (4) (the "Health Care Services Review statute"). Specifically, Wis. Stat. § 146.38(1m) provides:

No person who participates in the review or evaluation of the services of health care providers . . . may disclose an incident or occurrence report or any information acquired in connection with such review or evaluation. . . .

While the statute has several exceptions, there is no exception allowing providers to produce records covered by the statute pursuant to civil investigative demand. *See* Wis.

¹ Aurora has redacted or withheld a very small number of documents due to the application of the attorney-client privilege and the work-product doctrine.

Stat. § 146.38(3); (3m). In fact, subpoenas for such records are only enforceable if they are issued by “a court of record” for use in sexual exploitation cases. Wis. Stat. §§ 146.38(3)(dm); 895.441.

Case law demonstrates the breadth of the protection afforded to statutorily protected materials. For instance, courts have honored Wisconsin’s statutory protections in the following scenarios:

- Plaintiff not entitled to letter containing hospital’s peer review findings regarding surgeries defendant physician may have negligently performed on plaintiff even though the physician discussed the letter during his deposition (*Ollman v. Wis. Health Care Liabl. Ins. Plan*, 505 N.W.2d (Wis. Ct. App. 1993));
- Where provider requested state assistance in evaluating the provider’s infection quality assurance, plaintiff could not discover the Department of Health and Family Services’ report and conclusions or the provider’s meeting minutes and peer review results (*Braverman v. Columbia Hospital*, 629 N.W.2d 66 (Wis. Ct. App. 2001) (plaintiff was permitted to discover general statistical data not covered by the statute));
- Plaintiff could not discover hospital site surveys conducted by a third party service provider even though the reviews were general in nature and not related to specific incidents (*Hofflander v. St. Catherine’s Hospital, Inc.*, 664 N.W.2d 545 (Wis. 2003));
- Plaintiff not entitled to depose two hospital employees who investigated the cause of the plaintiff’s injuries; plaintiff instructed to seek the information from other sources (*Collura v. St. Mary’s Hospital of Milwaukee*, 618 N.W.2d 273 (Ct. App. Wisc. 2000)).

See also Wetzler v. Division of Hearings and Appeals, 797 N.W.2d 935 (rejecting the characterization of § 146.38 as a “peer review privilege” and referring to it as the “health care services review privilege”).

According to the Wisconsin Court of Appeals, the purpose of the Health Care Services Review statute is “to protect the confidentiality of the peer review process, in the hope that confidentiality would encourage free and open discussion, among physicians knowledgeable in an area, of the quality of treatment rendered by other physicians.” *Wisconsin v. Moroney*, 365 N.W.2d 887, 892 (Wis. Ct. App. 1985). Stated otherwise, “Wisconsin Stat. § 146.38 is designed to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care.” *Hofflander v. St. Catherine’s Hosp., Inc.*, 635 N.W.2d 13, 24 (Wis. Ct. App. (2001) (*affirmed in part, reversed in part* by *Hofflander v. St. Catherine’s Hosp., Inc.*, 664 N.W.2d 545, (Wis. 2008)); *see also Rechsteiner v. Hazelden*, 753 N.W.2d 496, 506 (Wis. 2008) (“Wisconsin Stat. § 146.38 complements § 146.37 and fosters the important policy of maintaining confidentiality in the review of health care services.”).

In its CID, the Government seeks documents that fall within the protection afforded by § 146.38, including peer review committee conclusions. In essence, the Government argues it is entitled to these documents because it is the federal government and not required to abide by state law. Notably, it makes no effort to fit within any exception to the statute, and thus implicitly concedes there is none.

II. FEDERAL LAW DOES NOT TRUMP THE WISCONSIN STATUTE.

Under the False Claims Act (“FCA”), the Court may modify or set aside a CID on account of “any constitutional or other legal right or privilege of the petitioner.” 31 U.S.C. § 3733 (j)(2)(B) (providing the standards for modifying or setting aside a CID). As described below, the Government’s motion should be denied on account of Aurora’s

statutory claims and because the documents the government seeks would not be admissible.

A. Federal Rule Of Evidence 501 Supports Recognizing The Statutory Privilege.

Federal Rule of Evidence 501 provides that privilege issues shall be governed by common law “as interpreted by United States courts in the light of reason and experience.” In turn, the Supreme Court has counseled that “the existence of a consensus among the States indicates that “reason and experience” support recognition of [a] privilege.” *Jaffe v. Redmond*, 518 U.S. 1, 13 (1995). Indeed, the committee notes accompanying Rule 501 also provide that “federal law should not supersede that of the States in substantive areas such as privilege absent a compelling reason.” The Seventh Circuit recognizes that “[a] strong policy of comity between state and federal sovereignties [that] impels federal courts to recognize state privileges where this can be accomplished at no substantial cost to federal substantive and procedural policy.” *Mem. Hosp. for McHenry Coun. V. Shadur*, 664 F.2d 1058, 1061 (7th Cir. 1981). Finally, Rule 501 was drafted to allow courts to determine if a privilege is appropriate on a case by case basis. *See U.S. v. Gillock*, 445 U.S. 360 (1980) (proposed Federal Rules of Evidence 501-513 which would have provided specific federal privileges bypassed to provide flexibility for case by case privilege decisions); *Advisory Committee Notes to Rule 501* (“. . . recognition of a privilege based on a confidential relationship and other privileges should be determined on a case-by-case basis.”). According to the Seventh Circuit, case-by-case determinations should be made by weighing the need for truth against the

importance of the policy sought to be furthered by the privilege and the likelihood that recognition of the privilege will in fact protect that policy. *Ryan v. Comm'r of Internal Revenue*, 568 F.2d 531, 542-43 (1977). Applying the principles above and the facts of this case, the documents sought by the government are protected from disclosure under the Wisconsin Health Care Services Review statute.

First, the Court should recognize Wisconsin's statutory protection as a matter of comity. As described above, the Wisconsin legislature enacted the protection of health care services review materials for the vitally important purpose of improving patient care in the state. Aurora justifiably relied on this protection to encourage its providers to participate in peer review activities. (Smith Affidavit ¶ 5); *see also, Lora v. Board of Education*, 74 F.R.D. 565 (E.D.N.Y. 1977) (where a "state holds out the expectation of protection to its citizens, they should not be disappointed by a mechanical and unnecessary application of the "federal rule"). Permitting discovery of the privileged documents simply to satisfy the Government's demands is not worth undermining the value of § 146.38. *See Ryan*, 568 F.2d at 542-43 (need for truth to be weighed against the importance of the policy sought to be furthered by the privilege). As a matter of comity, the health of Wisconsin's citizens should not be less important than the Government's investigation.

Second, recognition of the statutory protection is supported by the same considerations and Rule 501 analysis as the Supreme Court relied on in *Jaffee v. Redmond*, when it recognized a federal therapist-patient privilege. 518 U.S. at 13. Pursuant to *Jaffe*, "it is appropriate to treat a consistent body of policy determinations by

state legislatures as reflecting both [the] ‘reason’ and ‘experience’” referred to in Rule 501. *Id.* In light of this, the Court recognized a privilege, principally because it was already recognized by every state and the District of Columbia. *Id.* *Jaffe* also counsels that federal privileges must serve “public ends” and that mental and physical health of the citizenry satisfies this requirement as they are “a public good of transcendent importance.” *Id.* at 11. Conversely, the Court determined that the costs associated with recognizing a therapist-patient privilege were minimal. Specifically, the Court declared that if the privilege was not recognized:

[C]onfidential conversations between psychotherapists and their patients would surely be chilled, particularly when it is obvious that the circumstances that give rise to the need for treatment will probably result in litigation. Without a privilege, much of the desirable evidence to which litigants such as petitioner seek access—for example, admissions against interest by a party—is unlikely to come into being. This unspoken “evidence” will therefore serve no greater truth-seeking function than if it had been spoken and privileged.

Jaffee, 518 U.S. at 11-12.

This dispute is identical to the situation presented in *Jaffe*. The medical peer review privilege is now as deeply engrained in American jurisprudence as the therapist privilege was when *Jaffe* was decided; namely, every state and the District of Columbia has enacted a statute protecting peer review materials.² The peer review privilege, like

² See Ala. Code §6-5-333(D) (2008); Alaska Stat. §18.23.030(a) (2008); Ariz. Rev. Stat §36-445.01 (2008); Ark. Code Ann. §20-9-503 (West 2008); Cal. Evid. Code §1157 (West 2008); Colo. Rev. Stat. §25-3-109 (2008); Conn. Gen. Stat. §19a-17b (2008); Del. Code Ann. tit. 24, §1768 (2008); D.C. Code §44-805 (2008); Fla. Stat. Ann. §395.0193(8) (West 2008); Ga. Code Ann. §31-7-133(a) (West 2008); Haw. Rev. Stat. §624-25.5 (2008); Idaho Code Ann. §39-1392b (2008); 735 Ill. Comp. Stat. 5/8-2101 (2008); Ind. Code §34-30-15-1 (2008); Iowa Code Ann. §147.135(2) (West 2008); Kan. Stat. Ann. §65-4915(B) (2008); Ky. Rev. Stat. Ann.

the therapist-patient privilege, also serves “a public good of transcendent importance” by improving the health of the citizenry. *Jaffe*, 518 U.S. at 11. Likewise, if healthcare providers’ ability to engage in confidential peer review is defeated by the mere fact that a lawsuit is brought in federal versus state court, providers’ willingness to participate in peer review panels that improve the quality of health care services will be chilled and the type of documents the Government seeks in this case will cease to exist. This is particularly true today, where federal enforcement initiatives are increasingly common in the health care context. Accordingly, pursuant to *Jaffe* and FRE 501, the Court must justifiably recognize the protections provided by the Wisconsin Health Care Services Review statute.

Finally, the statutory protection can be upheld at very little cost to federal policy. *See Shadur*, 664 F.2d at 1061 (federal courts impelled to recognize state privileges where there is no substantial cost to federal policy). Most notably, the Wisconsin Health Care Services Review statute does not directly conflict with any federal law identified by the

§311.377(2) (West 2008); La. Rev. Stat. Ann. §13:3715.3 (West 2008); Me. Rev. Stat. Ann. Tit. 32, §2599 (2008); Md. Code Ann., Health Occ. §1-401 (2008); Mass. Gen. Laws Ann. Ch. 111, §204 (West 2008); Mich. Comp. Laws Ann. §331.533 (West 2008); Mich. Comp. Laws Ann. §331.20175 (West 2008); Minn. Stat. §145.64(1) (2008); Miss. Code Ann. §41-63-9(1) (2008); Mo. Rev. Stat. §537.035(4) (2008); Mont. Code Ann. §37-2-201(2) (2008); Neb. Rev. Stat. §71-2048 (2008); Nev. Rev. Stat. §49.265 (2008); N.H. Rev. Stat. Ann. §151:13-a (2008); N.J. Stat. Ann. §2A:84A-22.8 (2014); N.M. Stat. Ann. §41-9-5 (West 2008); N.Y. Pub. Health Law §2805-m (McKinney 2008); N.C. Gen. Stat. §131E-95(B) (2008); N.D. Cent. Code §23-34-03 (2008); Ohio Rev. Code Ann. §2305.252 (West 2008); Okla. St. Ann. Tit. 63, §1-1709 (West 2008); Or. Rev. Stat. §41.675(3) (2008); 63 Pa. Stat. Ann. §425.4 (West 2008); R.I. Gen. Laws §5-37.3-7 (2008); S.C. Code Ann. §40-71-20 (2008); S.D. Codified Laws §36-4-26.1 (2008); Tenn. Code Ann. §63-6-219(e) (West 2008); Tex. Occ. Code Ann. §160.007 (Vernon 2008); Utah Code Ann. §26-25-3 (West 2008); Vt. Stat. Ann. Tit. 26, §1443 (a) (2008); Va. Code Ann. §8.01-581.17 (West 2008); Wash. Rev. Code Ann. §4.24.250 (West 2008); W. Va. Code §30-3C-3 (2008); Wis. Stat. Ann. §146.38 (2008); Wyo. Stat. Ann. §33-26-408 (2008).

Government. The Government argues that the application of these protections in federal proceedings is belied by the absence of a peer review privilege in the Health Care Quality Improvement Act (“HCQIA”) and the FCA. (Moving Brief, pp, 10-12). However, the HCQIA and state peer review statutes can more easily be read as complementary, with the HCQIA providing the minimum protection afforded to peer review participants (that they typically cannot be liable for those actions), and state statutes providing additional protection in the form of insulating peer review documents from discovery. *See* 42 U.S.C. § 11137. Similarly, the privilege does not conflict with the FCA, as the FCA explicitly exempts the Government’s ability to issue CIDs for documents that are protected by a privilege. *See* 31 U.S.C. § 3733 (j)(2)(B).

Recognizing the statute would also have little impact on the Government’s investigation in this case. Aurora has produced more than 60,000 pages of documents to assist the Government in its investigation. The Government has failed to demonstrate that the withheld documents contain information that is not available in the previously produced documents or from less intrusive sources. In fact, the privileged documents have little to no value for the Government, because federal law prohibits using the records to prove liability in subsequent litigation. *See* Section II.C *supra*. Thus, recognizing the privilege would have little to no impact on federal policy or on potential future lawsuits against Aurora and/or its physicians.

The Government’s interest in obtaining the protected documents does not trump State law but rather pales in comparison to Wisconsin’s “transcendent” public interest in allowing healthcare providers to confidentially evaluate and improve the effectiveness of

life saving techniques and procedures. *Jaffee*, 518 U.S. at 11 (recognizing a “transcendent” interest in the health of citizens). As the Government has failed to demonstrate a compelling need for the documents and because the value of the documents is far outweighed by the impact it would have on peer review actions, the Government’s motion should be denied. *See Advisory Committee Notes to Rule 501* (“federal law should not supersede that of the States in substantive areas such as privilege absent a compelling reason.”).

B. The Motion Should Be Denied In Light Of The Self-Critical Review Privilege.

Additionally, the Court should deny the Government’s motion based on the federally recognized self-critical review privilege. The self-critical review privilege protects materials and information: (1) that result from a critical self-analysis; (2) of which the public has a strong interest in preserving the creation and distribution; and (3) that would cease to be created if discoverable. *See Reichhold Chems. Inc. v. Textron, Inc.*, 157 F.R.D. 522, 527 (N.D. Fla. 1994). The privilege was first recognized to protect materials similar to those protected by the Wisconsin Health Care Services Review statute. *See Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970), *aff’d*, 479 F.2d 920 (D.C. Cir. 1973) (hospital staff meeting minutes regarding patient care protected from discovery due to public interest in having hospitals critically evaluate and improve

quality of the care). Subsequently, the self-critical review privilege has been applied almost exclusively to protect peer review and medical evaluation materials.³

The documents at issue here qualify for protection under the self-critical review privilege. The records were created for the purpose of analyzing and improving the services Aurora provides to its patients. (Declaration of Barbara Fleming in Opposition to United States' Petition to Enforce Civil Investigative Demand ("Fleming Decl.") at ¶¶ 5.) Moreover, as courts have recognized, "the self-critical analysis privilege is particularly pertinent in the medical context as it promotes frank and honest discussions which protect lives and improve patient care." *Weekoty*, 30 F. Supp.2d at 1345 (*citing* Charles David Creech, Comment, *The Medical Review Committee Privilege: A Jurisdictional Survey*, 67 N.C. L. REV. 179 (1988)). And finally, if these materials "were open to discovery and public rebuke, physicians would not be as frank or candid and the goal of improving medical care would be substantially undermined." *Id.* at 1345-

³ See, e.g., *Balk v. Dunlap*, 163 F.R.D. 360, 363 (D. Kan. 1995) (minutes of meeting regarding patient care protected under Kansas peer review privilege); *Brem v. Decarlo, Lyon, Hearn & Pazoureck, P.A.*, 162 F.R.D. 94, 98-99 (D. Md. 1995) (applying state medical peer review privilege in a federal question case); *Spinks v. Children's Hospital Nat'l. Med. Cnt.*, 124 F.R.D. 9, 12 (D.D.C. 1989) (applying District of Columbia's privilege to protect morbidity and mortality conference materials); *Weekoty v. U.S.*, 30 F. Supp.2d 1343, 1344-1347 (D. N.M. 1998) (recognizing self-critical review privilege to protect morbidity and mortality conference materials); *Utterback v. Yoon*, 121 F.R.D. 297 (W.D. Ky. 1987) (quality assurance records and memorandum exempt from discovery in Federal Tort Claims Act case); *Gillman v. U.S.*, 53 F.R.D. 316, 318-19 (S.D.N.Y. 1971) (hospital's suicide investigation reports not discoverable); but see, *Burden-Meeks v. Welch*, 319 F.3d 897 (7th Cir., 2003) (privilege has yet to be recognized by the 7th Circuit).

46. Consistent with the cases above, the Government's motion should be denied pursuant to the self-critical review privilege.

C. HCQIA Immunity Prevents The Government From Using The Documents To Establish Liability.

With the exception of civil rights claims, the HCQIA grants immunity from damages "under any law of the United States or of any State" relating to the provider's participation in peer review activities. 42 U.S.C. § 11111(a). In the context of this investigation, the Government's attempt to obtain peer review documents appears to be aimed at proving elements of a future FCA claim. (*See* Government's Brief, pp. 1-3) (detailing the Government's investigation and the need for the documents to pursue potential FCA claims). Because the HCQIA precludes the Government from holding Aurora or participating individuals liable for peer review-related actions conducted in accordance with the statute, the documents at issue are not "reasonably relevant" to Government's investigation and are not properly discoverable by way of a CID. *See* 31 U.S.C. § 3733(a)(1); *EEOC v. Quad/Graphics*, 63 F.3d 642, 645 (7th Cir. 1995) (CIDs may only be used to secure information that is "reasonably relevant" to an investigation). Accordingly, the Government's motion should be denied.

III. PUBLIC POLICY DICTATES THAT THE DOCUMENTS AT ISSUE BE PROTECTED.

Wisconsin's legislature enacted the statute for the express purpose of "encourag[ing] candid and voluntary studies and programs used to improve hospital conditions and patient care" and to "improve the overall quality of services [Wisconsin's physicians] provide." *Hofflander*, 247 Wis. 2d at 636. Relying on this protection,

Aurora undertakes significant introspective actions to identify and correct potential shortcomings in the care it provides. (Fleming Decl. at ¶¶ 2-4; Smith Decl. at ¶¶ 2-3, 6.) Forcing Aurora to produce documents related to these actions, especially for the purpose of assisting the Government in proving potential wrongdoing on Aurora's and/or its physicians' part, will chill and limit Wisconsin physicians' and healthcare providers' willingness to take part in peer review initiatives in the future. Indeed, invading the privilege will likely suppress physician interaction in statutorily-protected activities throughout Aurora's entire system, which includes hospitals where there is currently no governmental suspicion of wrongdoing. In turn, this could decrease the standard of care provided to Wisconsin citizens. Wisconsin's attempt to improve and maintain its healthcare system should not be circumvented when its legislative policy is so clear.

IV. GRANTING THE MOTION WOULD SUBJECT AURORA TO UNJUST EXPOSURE TO LIABILITY.

While the Government attempts to frame this as nothing more than a privilege dispute, granting the pending motion would force Aurora to violate a substantive statute and could subject Aurora to litigation. The Wisconsin Health Care Review Services statute provides a private right of action to anyone impacted by an unlawful release of peer review records. Wis. Stat. § 146.38(4). Thus, if Aurora is forced to produce protected documents, it opens the door to potential claims from participants in the peer review process, peer review subjects, and/or any patients who may be impacted by the released records.

Aurora's concerns regarding potential liability are not illusory, as demonstrated by *Turk v. Oiler*. 732 F. Supp. 2d 758 (N.D. Ohio 2010). The plaintiff in *Turk* sued Cleveland Clinic for invasion of privacy because the clinic produced his protected medical records in violation of Ohio law. Cleveland Clinic moved to dismiss the claim on the grounds that it produced the documents pursuant to a grand jury subpoena, which assisted the grand jury in investigating whether the plaintiff had participated in criminal activity. Cleveland Clinic also argued that plaintiff had no cause of action, because the documents were reviewed in secret and only by the grand jury. Despite the fact that the records had been subpoenaed and were used to investigate potential criminal activity, the court denied the clinic's motion to dismiss, because the Ohio statute which prohibited the release of the records did not "contain any exceptions permitting disclosure of otherwise privileged medical information simply because the information is sought via grand jury subpoena." 732 F. Supp. 2d at 770-74. Again, Wisconsin law provides no exception allowing protected records to be released pursuant to a subpoena or FCA civil investigative demand. Thus, unless the statute is ignored, the petition must be denied.

The Government also claims Aurora need not worry because the records will be kept secret and cannot be disseminated pursuant to the FCA. (Government Brief, p. 14.) This position is both incorrect, *see* 31 U.S.C. § 3733(a)(1)(D) (permitting information to be shared with any *qui tam* relator), and insufficient to protect Aurora from litigation (as demonstrated by *Turk*).

CONCLUSION

At its heart, the Government's position is simply that it is not subject to the laws of a state sovereign. Its supremacy argument comes with a high price: eliminating the ability and incentive for healthcare providers, including those not under investigation, to confidentially explore the quality of care already provided, as well as whether they can provide better, safer care for future patients. Because this price is too high, and in light of Rule 501, Supreme Court precedent, Wisconsin law and the self-critical review privilege, the Court should deny the Government's petition.

Date: January 20, 2015

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